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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/928,198
Filing Date: August 10, 2001
Appellant(s): HOFFMANN ET AL.

Paula K. Davis
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 20 September 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct. Of course, the Examiner disagrees with the conclusion drawn by Appellant, for reasons of record.

(6) Issues

The Appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Keene *et al.,* The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (1989).

Skrabanja *et al.,* EP 0853 945 A1.

Andya *et al.,* US Patent No. 6,267,958 B1.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the proposed claim amendment:

Claim Rejections - 35 USC § 103

Claim 128 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keene *et al.,* The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (1989) in view of Skrabanja *et al.,* EP 0853 945 A1 (cited in IDS, reference #BF) and Andya *et al.,* US Patent No. 6,267,958 B1 (cited in last Office Action).

The instant claims are drawn to a pharmaceutically acceptable solution formulation comprising human FSH (concentrations 5.0ug/ml to 2mg/ml) and benzyl alcohol in an aqueous diluent, wherein the FSH consists of an α-subunit having SEQ ID NO:5 and a β-subunit having SEQ ID NO:6 held together by noncovalent interactions and the formulation is suitable for multi-dose administration by injection.

Keene *et al.* teach the expression of biologically active recombinant human follicle-stimulating hormone (FSH) (abstract, page 4769, 3rd paragraph; page 4771, 3rd paragraph and 6th paragraph). Human FSH α subunit is SEQ ID NO:5 (1-92 amino acids). Human FSH β subunit is SEQ ID NO:6 (1-111 amino acids). Keene *et al.* describe the construction and expression of human FSH α and β subunit (page 4770,

first paragraph). Keene *et al.* teach the biological activity of recombinant human FSH (page 4772, 2nd paragraph-page 4773 and Figures 6, 7). Keene *et al.* do not disclose pharmaceutical formulations of recombinantly expressed human FSH with benzyl alcohol suitable for multi-use administration by injection.

Skrabanja *et al.* teach a stable pharmaceutical formulations comprising liquid FSH (abstract; page 3, lines 15-18, 35-38 and page 4, lines 11-13). Liquid FSH comprises all forms including human recombinant FSH (page 3, lines 35-54). Skrabanja *et al.* teach concentrations of FSH, which overlap the concentrations in the instant claims (page 5, lines 5-14). Skrabanja *et al.* teach an article of manufacture comprising a vial or a pen-injector device. The liquid formulation can be in the form of a cartridge for multiple uses (i.e. human FSH formulation that is suitable for multi-dose administration by injection) (page 5, lines 21-45).

Andya *et al.* teach stable lyophilized protein formulations, which when reconstituted generates a stable multi-use formulation (column 1, lines 52-column 2, line 9). The reconstituted formulation may be used as a multi-use formulation (column 2, lines 20-30). Andya *et al.* teach the follicle-stimulating hormone (FSH) as a suitable protein in the formulation (column 6, lines 44-50). Andya *et al.* teach that a preservative can be added to the diluent to reduce bacterial action in the reconstituted formulation, thus facilitating the production of a multi-use reconstituted formulation. Examples of preservatives include benzyl alcohol (column 9, lines 46-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the human FSH of Keene, by formulating it as a

pharmaceutical composition with benzyl alcohol suitable for multi-use administration by injection as suggested by Skrabanja and Andya with a reasonable expectation of success. The motivation and expected success is provided by Skrabanja and Andya, in that Skrabanja *et al.* teach pharmaceutical formulations comprising FSH concentrations which can be used in stable multi-use liquid pharmaceutical formulations and Andya *et al.* teach that pharmaceutical multi-use formulations comprising FSH can have preservatives such as benzyl alcohol to reduce bacterial action.

Double Patenting

Claim 128 is provisionally rejected under the judicially created doctrine of double patenting over claims 159 and 160 of copending Application No. 09/744,431 in view of Keene et al., The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (1989), Skrabanja et al., EP 0853 945 A1 and Andya et al., US Patent No. 6,267,958 B1.

This rejection was made in the Final Office action dated 18 March 2004. Appellant's amendment (20 October 2003) necessitated the new grounds of rejection presented in the Final Office action. Appellants have stated that a terminal disclaimer will be filed upon the allowance of claim 128.

(11) Response to Argument

A. Claim Rejections Under 35 U.S.C. 103(a)

Appellant summarizes the arguments for Section I and Section II as follows. Regarding Section I, at page 5, second paragraph of the Brief, Appellant argues that the

Examiner improperly picked and chose elements of the claimed invention from the prior art to reconstruct the invention in hindsight, using the present application as the motivation for combining rather than finding the motivation for combining in the references themselves. Appellant argues that the Examiner ignored the art teaching that aqueous solutions of FSH are unstable and that the Examiner failed to acknowledge that the ordinarily skilled artisan knew that adding preservatives to solutions having a low concentration of protein, at best, is unpredictable and with some proteins, was thought to destabilize the protein. Appellant states that Section I establishes that claim 128 is not prima facie obvious over the combination of references cited by the Examiner.

Regarding Section II, at page 5, last paragraph of the Brief, Appellant states that this section provides compelling evidence, even if a prima facie case is established, that the claimed invention is not obvious. Appellant argues that because for about thirty years prior to the present invention, the treatment regimen for FSH required the patient to reconstitute one or more doses per day over a period of about two weeks, a long-felt need existed for a preserved aqueous FSH formulation suitable for multi-dose administration by injection for at least thirty years. Appellant argues that the stability of low concentrations of FSH formulated with benzyl alcohol is unexpected in view of the prior art of record and when FSH solutions preserved with benzyl alcohol were introduced for sale, they quickly demonstrated commercial success. Appellant argues that these secondary considerations rebut any prima facie showing and provide compelling evidence of patentability.

Appellant has summarized the arguments for Section I and Section II. The Examiner will address each section individually. Starting at Section I, bottom of page 4 of the Brief, Appellant argues that references cited by the Examiner do not create a prima facie case of obviousness. Appellant states that claim 128 provides a solution formulation comprising low concentrations of human FSH and benzyl alcohol in an aqueous diluent. Appellant states that the claim limits the formulation such that it must have an human FSH concentration in the range of 5.0 μg/mL to 2 mg/mL, it must contain specific α- and β-subunit protein sequences corresponding to human FSH that are held together by non-covalent bonds, and it must be suitable for multi-dose administration by injection. At the middle of page 5 of the Brief, Appellant cites case law. Appellant argues that the Examiner provides no objective evidence that teaches, suggests, or motivates one to combine the cited references.

Appellant's arguments have been fully considered, but are not deemed persuasive. The Examiner has fully addressed each reference cited in the maintained 35 USC 103(a) rejection. The Examiner discussed what was taught, the motivation and expected success. The three references, **when combined**, teach all of the claim limitations (Emphasis added). The Examiner will further demonstrate that the references, when combined, create a case of prima facie obviousness.

At the top of page 6 of the Brief, Appellant argues against the Skrabanja reference. Appellant states that Skrabanja describes problems associated with the stability of FSH, indicating that this instability led to FSH being supplied as a lyophilized product that must be reconstituted. At the bottom of page 6 of the Brief, Appellant

argues that no antimicrobial preservatives, such as benzyl alcohol are included in the examples of Skrabanja. At the middle of page 7 of the Brief, Appellant states that the Examiner stresses that Skrabanja provides a cartridge for multiple use. Appellant argues that when taken in context, Skrabanja use of the term "multiple use", neither means nor suggest that the product is preserved, should be preserved or even could be preserved. At the middle of page 7 of the brief, Appellant states that although Skrabanja makes no mention of any preservative despite a very detailed comprehensive teaching, it clearly specifies that its formulation are sterile. Appellant contends that Skrabanja's sterile formulation, although unpreserved could be considered a multiple use product, but provides no teaching, motivation, or suggestion to add any preservative generally or benzyl alcohol specifically to a liquid FSH formulation. Appellant argues that the Examiner fails to provide any evidence explaining why a person of ordinary skill in the art would alter Skrabanja's stable formulation.

The Examiner understands that Appellant is arguing against the Skrabanja reference because it states that FSH is supplied as a lyophilized product that must be reconstituted and it provides no teaching, motivation, or suggestion to add any preservative generally or benzyl alcohol specifically to a liquid FSH formulation. Appellant's arguments have been fully considered but are not deemed persuasive because the MPEP 2143 states that the prior art reference **(or references when combined)** must teach or suggest all the claim limitations (Emphasis added). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The maintained 103(a) rejection was based on the combination of the references (Keene, Skrabanja and Andya). Furthermore, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claim recites "a pharmaceutically acceptable, solution formulation comprising....". **The claims do not recite wherein FSH is not reconstituted** (Emphasis added). The Skrabanja reference teaches concentrations of FSH which overlap with the concentrations in the instant claims and provides the motivation for a human FSH solution formulation that is suitable for multi-dose administration by injection (Skrabanja *et al.,* page 5, lines 5-14).

At the bottom of page 8 of the Brief, Appellant argues against the Andya reference. Appellant states that the object of Andya is to provide a lyophilized formulation, that when reconstituted, provides a very high protein concentration. Appellant asserts that Andya requires a concentration greater than or equal to 50 mg protein/mL diluent. Appellant argues that Andya does not teach or suggest that a lower concentration protein formulation would be stable.

Appellant's arguments have been fully considered, but are not deemed persuasive. Andya *et al.* state, "In particular, while the protein concentration in the pre-lyophilized formulation may be 5 mg/mL or less, the protein concentration in the reconstitution formulation is generally 50 mg/mL or more". "Such high protein concentrations in the reconstituted formulation are considered to be particularly useful where the formulation is intended for subcutaneous administration". Most importantly,

Andya *et al.* state, "Despite the very high protein concentrations in the reconstituted formulation, it has been found that the reconstituted formulation is stable (i.e. fails to display significant or unacceptable levels of chemical or physical instability of the protein) at 2-8° C. for at least about 30 days". Thus, the Andya patent suggests **that *higher* concentrations** of proteins in the reconstituted formulation could *potentially* be unstable, **not lower concentrations** (Emphasis Added).

At the bottom of page 9, Appellant argues that a preservative is mentioned as an optional excipient in the diluent used for reconstitution. Appellant argues that Andya does not describe any stability effects of the preservative. At page 10 of the Brief, Appellant argues that the mere fact that Andya contains a long list of proteins for possible use in its invention does not teach, motivate, or suggest to the person of skill in the art that all proteins in the list can be formulated with all the other excipients disclosed in the patent. At the middle of page 10 of the Brief, Appellant asserts that benzyl alcohol, Andya's preferred preservative and the preservative used in the instant invention, has been shown to having a destabilizing effect on some of the proteins named in Andya's list (human growth hormone, interferon-gamma and insulin growth factor). Appellant cites references to support the assertion. Appellant states that the references cited are ample evidence that one skilled in the art would plainly recognize that all proteins on Andya's list are not compatible with all the other excipients disclosed, particularly preservatives and would not be motivated to pick and choose FSH and benzyl alcohol from the list of proteins and the list of optional excipients, respectively as the Examiner has done.

Appellant's arguments have been fully considered, but are not deemed persuasive. Appellant argues that a preservative is mentioned as an optional excipient in the diluent used for reconstitution. This is not found persuasive because Andya *et al.* clearly state that benzyl alcohol is added to the diluent to reduce bacterial action in the reconstituted formulation, thus facilitating the production of a multi-use reconstituted formulation (column 9, lines 46-59). Secondly, the stability effect of the preservative is not a limitation of claim 128. Thus, the Andya patent does not have to describe the stability effects of benzyl alcohol. Furthermore, the references cited by Appellant **do not teach** the destabilizing effects of FSH and benzyl alcohol (Emphasis added). The references cited by Appellant teach the **destabilizing effects of other proteins and benzyl alcohol** (Emphasis added). **Thus the references cited do not teach away from using FSH and benzyl alcohol** (Emphasis added). Lastly, the Examiner cannot comment on the validity of an issued patent. The disclosure and claims of the Andya patent are presumed to be fully enabled.

At the top of page 11 of the Brief, Appellant asserts that even though it was known and immediately apparent to a skilled artisan that some of the 100-plus proteins in Andya's list would not be compatible with some of the optional excipients, the Examiner does not address this knowledge of destabilizing effects. Appellant argues that the knowledge generally available to one skilled in the art of protein formulation science suggest unpredictability and compatibility problems between preservatives and proteins. Appellant cites a reference. At the bottom of page 11 of the Brief, Appellant argues that Andya provides no expectation of success for each and every combination

of proteins and excipients disclosed in the Andya patent. Appellant maintains that Andya provides no expectation of success for combinations of FSH with benzyl alcohol, especially for a combination having a concentration far lower than Andya teaches.

The Examiner understands that Appellant is arguing against the Andya patent because benzyl alcohol has been shown to having a destabilizing effect on some of the proteins named in Andya's list. Appellant's arguments have been fully considered but are not deemed persuasive. As was stated above, the references cited by Appellant teach the destabilizing effects of other proteins and benzyl alcohol. The Andya patent teaches lyophilized protein formulations (FSH), which can be reconstituted with a diluent to generate a stable reconstituted formulation suitable for administration. Benzyl alcohol is added to the diluent to reduce bacterial action in the reconstituted formulation, thus facilitating the production of a multi-use reconstituted formulation (column 1, lines 10-16, column 6, lines 44-50 and column 9, lines 46-59). The disclosure and claims of the Andya patent are presumed to be fully enabled. The Examiner has already addressed the arguments regarding the stability of low protein concentrations with benzyl alcohol. The Andya patent suggests that higher concentrations of proteins in the reconstituted formulation could potentially be unstable, not lower concentrations.

At the top of page 12 of the Brief, Appellant argues that Keene *et al.* do not teach, suggest or motivate a person of skill in the art to make any formulation of FSH. Appellant maintains that Keene provides the sequence of human FSH and how to express it recombinantly. At the middle of page 12, Appellant cites case law and argues that none of the references taught, suggested or motivated one skilled in the art to

combine the references. At the top of page 13 of the Brief, Appellant argues that the art explicitly taught the addition of a preservative to FSH would lead to degradation, especially in a low concentration solution formulation. Appellant cites Donaldson *et al.* as a reference, which teaches away from using FSH with benzyl alcohol. Appellant argues that the fact that all of the FSH formulations were provided in lyophilized forms for reconstitution immediately before use strongly suggested to a person of ordinary skill in the art either that FSH was unstable in solution or that it could not be stably formulated with a preservative. Appellant cites references to demonstrate the instability of FSH.

Appellant's arguments have been fully considered but are not deemed persuasive. As was stated above, the maintained 35 USC 103(a) rejection is based on a combinations of references. Contrary to Appellant's assertion, the Examiner did not perform hindsight reconstruction. The Examiner did not ignore the general knowledge in the art and specific teachings in the references. Keene *et al.* teach the expression of biologically active recombinant human FSH (FSH α subunit SEQ ID NO:5 and β subunit is SEQ ID NO:6). Skrabanja *et al.* teach concentrations of human recombinant FSH solution formulations (which overlap the concentrations in the instant claims) that can be in the form of a cartridge for multiple uses. Andya *et al.* teach that benzyl alcohol is added to the diluent to reduce bacterial action in the reconstituted formulation (comprising FSH), thus facilitating the production of a multi-use reconstituted formulation. Appellant cites Donaldson *et al.* as a reference, which teaches away from using FSH with benzyl alcohol. Donaldson *et al.* **published November 1992**, (U.S.

patent cited by Appellant) may teach that preservatives, other than thymol, damage FSH and cause instability of the product (Emphasis Added). However, Andya *et al.*, **published July 2001**, teach benzyl alcohol as a preservative, which can be added to the diluent to reduce bacterial action in the formulation comprising FSH (Emphasis Added). Thus, besides the Donaldson patent (published 13 years ago), no references submitted **specifically** teach that benzyl alcohol would denature/destabilize FSH in solution (Emphasis added).

At Section II, bottom of page 14 of the Brief, Appellant argues that the preserved FSH formulations of the instant application are not obvious because they fulfilled a long felt but unresolved need for multidose, preserved FSH solutions and the conformational stability was unexpected. Appellant cites case law. At page 15 of the Brief, Appellant once again argues against the references cited by the Examiner in the maintained 35 USC 103(a) rejection. Appellant argues the differences between the prior art and the claimed invention. At page 16 of the Brief, Appellant discusses the level of skill in the art. At the bottom of page 16 of the Brief, Appellant cites case law pertaining to evidence of long-felt but unresolved need.

The Examiner understands that Appellant maintains that the instant invention is not obvious because it fulfilled a long felt but unresolved need for multidose, preserved FSH solutions and that the conformational stability was unexpected. Appellant argues against the references cited by the Examiner in the maintained 35 USC 103(a) rejection and states the differences between the prior art and the claimed invention, by addressing the references individually. Appellant's arguments have been fully

considered but are not deemed persuasive because there can be no long felt need in the face of literature suggesting the opposite. Skrabanja *et al.* teach multi-dose stable liquid formulations comprising FSH, polycarboxylic acid and a thoiether compound. Andya *et al.* teach the instant invention, multi-dose stable liquid formulations comprising FSH and benzyl alcohol. The Examiner has already addressed each reference cited in the maintained 35 USC 103(a) rejection. The Examiner discussed what was taught, the motivation and expected success. As was previously stated, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

At the top of page 17 of the Brief, Appellant discusses the Declaration of Dr. John M. Beals submitted with the Brief under 37 CFR 1.132. Appellant characterizes the Beals declaration as establishing the recognized instability of FSH and the evidence of non-obviousness. Appellant states that Dr. Beal's declaration describes FSH products for use in humans that were available for sale over the thirty years prior to the claimed invention. Appellant contends that six products were marketed, none of which contained an antimicrobial preservative. Appellant argues that each product was provided in single-dose vials or cartridges, despite dosing requirements that required multiple injections. Appellant states that Dr. Beals' declaration describes another gonadotropin, hCG, which has been formulated for use as a solution preserved with benzyl alcohol since 1965. Appellant argues that the fact that the present invention was needed far more than the know multidose hCG products is evidence of non-obviousness.

The Examiner understands that Appellant is arguing a case of nonobviousness for the instant invention because the record shows that pharmaceutical companies provided FSH in lyophilized form for reconstitution immediately before use and that each product was provided in single dose vials. Thus, Appellant's argument is that the instant invention is nonobvious because it was never disclosed, produced or marketed. Appellant's arguments have been fully considered but are not deemed persuasive. Andya *et al.* teach the instant invention, multi-dose stable liquid formulations comprising FSH and benzyl alcohol. Therefore, Appellant's argument that the instant invention is nonobvious because it was never disclosed, produced or marketed is not persuasive. The Beals declaration under 37 CFR 1.132 filed 20 September 2004 is insufficient to overcome the rejection of claim 128 based upon 35 USC 103(a) rejection as set forth in the last Office action. As an aside, it is noted that Dr. Beals is an employee of Eli Lilly and Company, the real party in interest in this appeal. One skilled in the art would not be dissuaded from using benzyl alcohol with FSH, because Dr. Beals teaches that hCG, **a protein that is related structurally to FSH, can be preserved with benzyl alcohol** (Emphasis Added).

At the top of page 18 of the Brief, Appellant argues that FSH is unstable and in light of its instability, FSH was often stored as a lyophilized powder to be reconstituted with solvent immediately before use. Appellant states that the addition of preservatives to protein solutions was known to cause degradation of the protein in some solutions. Appellant cites references. At the bottom of page 18 of the Brief, Appellant argues that the conformational and physical stability of one protein cannot be predicted from the

successes and failures of others. Appellant contends that knowing the instability of FSH and the destabilizing effects of preservatives on some proteins, the person of ordinary skill in the art would not have expected a stable formulation of FSH and benzyl alcohol. Appellant argues that in the preserved formulation of the instant invention, the FSH heterodimer exhibits comparable physical and conformational stability to an unpreserved control FSH solution that lacks benzyl alcohol. At the top of page 19 of the Brief, Appellant contends that the results were surprising considering the statement by Donaldson, teaching away from the use of benzyl alcohol. Appellant states the Beals declaration establishes the need for a stable FSH solution formulation.

The Examiner understands that Appellant is arguing that the fact that FSH formulations were provided in lyophilized forms for reconstitution make a case that either FSH was unstable in solution or could not be stably formulated with preservative. Appellant's arguments have been fully considered but are not deemed persuasive. Appellant has overlooked the Andya *et al.* reference, which teaches multi-dose stable liquid formulations comprising FSH and benzyl alcohol. Appellant lists a number of unrelated proteins that degrade in the presence of a preservative. However, hCG, a protein that is related structurally to FSH, can be preserved with benzyl alcohol. Appellant cites Donaldson *et al.* again, as a reference, which teaches away from using FSH with benzyl alcohol. As was stated above, Andya *et al.,* published July 2001, teach benzyl alcohol as a preservative, which can be added to the diluent to reduce bacterial action in the formulation comprising FSH. Thus, besides the Donaldson patent (published 13 years ago), no references submitted **specifically** teach that benzyl

alcohol would denature/destabilize FSH in solution (Emphasis added). There is no evidence that FSH would be expected to behave differently in benzyl alcohol.

At the middle of page 19 of the Brief, Appellant cites case law. Appellant states that since the effective date of filing the instant invention, two multi-dose FSH products preserved with benzyl alcohol, have been launched. Appellant argues that the commercial success of these products provide further evidence that the present invention provided a significant and nonobvious advance over the art and is therefore patentable.

Appellant's arguments have been fully considered but are not deemed persuasive. The Examiner finds Appellant's arguments against the Andya *et al.* reference (because FSH was initially lyophilized) and general arguments against lyophilized FSH, very confusing. It is noted that Gonal-f® Multi-Dose, cited by Appellant as an FSH composition with commercial success, must be first reconstituted. This means that the Gonal-f® Multi-Dose product is lyophilized. Appellant states, "For a showing of commercial success, the record must show a sufficient nexus between this commercial success and the patented invention". Appellant cites *Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579, 42 U.S.P.Q.2d 1378, 1384* (Fed. Cir. 1997). However, the case summarizes by stating "in sum, the record supplies objective evidence of nonobviousness, including Baxter's recognition of the importance of this invention, evidence of commercial success, and evidence of the failure of others to solve the recognized problem". "This objective evidence, combined with the lack of a teaching or suggestion to combine, requires a holding of nonobviousness." The

Examiner has cited literature, which teaches stable multi-dose pharmaceutical solution products comprising FSH (Skrabanja *et al.*) The Examiner has cited literature, which teaches stable multi-dose pharmaceutical solution products comprising FSH and benzyl alcohol (Andya *et al.*). When all of the evidence is considered, the evidence of nonobviousness fails to outweigh the evidence of obviousness.

B. Claim Rejections Under Double Patenting

At the bottom of page 21 of the Brief, Appellant states that the Examiner has provisionally rejected claim 128 under the judicially created doctrine of double patenting over claims 159 and 160 of copending Application No. 09/744,431 in view of Keene *et al.,* The Journal of Biological Chemistry Vol. 264/9: 4769-4775 (1989), Skrabanja *et al.,* EP 0853 945 A1 and Andya *et al.,* US Patent No. 6,267,958 B1. At the top of page 22 of the Brief, Appellant cites MPEP 804.02. Appellant states that they have offered to file a terminal disclaimer on October 16, 2003 and the rejection should have been held in abeyance pending resolution of this appeal. Appellant maintains that because the rejection was stated in the final rejection, a terminal disclaimer will be filed upon the allowance of claim 128, thereby obviating the obviousness-type double patenting rejection.

As was stated above, the obviousness-type double patenting rejection was made in the Final Office action dated 18 March 2004. Applicant's amendment (20 October 2003) necessitated the new grounds of rejection (obviousness-type double patenting rejection) presented in the Final Office action. Since claim 128 is not allowable other

than for the obviousness-type double patenting rejection, the obviousness-type double patenting rejection is properly maintained. The issue of the 35 U.S.C. 103 (a) rejection and ultimately the obviousness-type double patenting rejection will be reserved for ruling by the Board of Patent Appeals and Interferences.

Therefore, for reasons set forth above, Appellants arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the case of 35 U.S.C. 103(a) obviousness and it is believed that the rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

RMD
January 3, 2005

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